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NON-PROVISIONAL
UTILITY PATENT APPLICATION
TRANSMITTAL - 37 CFR 1.53(b)

☐ Duplicate
(check, if applicable)

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Washington, DC 20231

Attorney Docket No. 8056-80 (E 1875)
First Named Inventor: Hans Grundei *et al.*
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Total Pages of Transmittal Form: 2

Transmitted herewith for filing is the **non-provisional** utility patent application entitled:
FEMUR ENDOPROSTHESIS FOR ARTIFICIAL HIP JOINT

which is:

an ☒ Original; or

a ☐ Continuation, ☐ Divisional, or ☐ Continuation-in-part (CIP)
of prior Application No. /, filed .

☐ This non-provisional patent application is based on Provisional Patent Application
No. , filed .

Enclosed are:

- ☒ Specification (including Abstract) and claims: 9 pages.
- ☒ Newly executed Declaration (facsimile copy).
- ☐ Copy of Declaration from prior application.
- ☐ Separate Power of Attorney (including 37 CFR 3.73(b) statement, if applicable).
- ☒ 1 sheets of drawings (formal) plus one copy.
- ☐ Microfiche computer program (Appendix).
- ☐ Nucleotide and/or Amino Acid Sequence Submission, including:
 - ☐ Computer readable copy ☐ Paper Copy ☐ Verified Statement.
- ☐ Under PTO-1595 cover sheet, an assignment of the invention.
- ☐ Certified copy of Application No. , filed , is filed:
 - ☐ herewith or ☐ in prior application .
- ☒ Verified Statement claiming Small Entity Status under 37 CFR 1.9 and 1.27.
 - ☐ was filed in the prior non-provisional application, and such status is still proper and desired (37 CFR 1.28(a));
 - ☒ is enclosed herewith; ☐ is no longer desired.
- ☐ Preliminary Amendment.
- ☐ Information Disclosure Statement, PTO-1449, and cited references.
- ☐ Other:

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The filing fee has been calculated as shown below:

			SMALL ENTITY			LARGE ENTITY	
CLAIMS	NO. FILED	NO. EXTRA	BASIC FEE: \$395.			BASIC FEE: \$790	
Total	6-20=	-0-	X11	\$	OR	X22	\$
Independent	1- 3=	-0-	X41	\$	OR	X82	\$
Multiple Dependent Claims Present			\$135	\$	OR	\$270	\$
			TOTAL	\$395.00	OR	TOTAL	\$

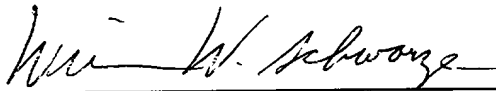
The Commissioner is hereby authorized to charge payment of the following fees or credit any overpayment to Deposit Account No. 16-0235. One additional copy of this sheet is enclosed.

- ☒ The above calculated filing fee **\$395.00**.
- ☒ Any additional fees required under 37 C.F.R. § 1.16.
- ☒ Any additional fees required under 37 C.F.R. §1.17.
- ☒ If the filing of any paper during the prosecution of this application requires an extension of time in order for the paper to be timely filed, applicant(s) hereby petition(s) for the appropriate extension of time pursuant to 37 C.F.R. §1.136(a).

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WWS/ml
Enclosures

TITLE

Femur Endoprosthesis for Artificial Hip Joint

BACKGROUND OF THE INVENTION

5 The present invention is directed to a femur endoprosthesis for an
artificial hip joint, which is an alternative to the femur endoprosthesis in accordance
with German patent 196 01 340 (U.S. patent application 08/783,476, the disclosure of
which is incorporated herein by reference).

10 Essentially two treatment possibilities have proven themselves during
recent decades for treatment of a destroyed hip joint head from which considerable pain
sensations and serious functional restrictions of the joint result:

First, it is possible to provide the patient with an orthotic device, that is
with an external support apparatus. In addition to the fact that this therapeutic
possibility is completely unacceptable from a cosmetic point of view, it is also less than
optimal from the perspective of therapeutic technology.

15 A further, more widely accepted possibility is to provide the patient with
an endoprosthesis, namely a hip stem endoprosthesis, in which a stem is installed in the
previously excavated bone marrow area of the femur and is there fixed with or without
the use of cement. Such an endoprosthesis then offers the possibility of connection on
its proximal side with an artificial spherical joint part.

20 It is precisely the latter possibility which is strongly represented in
patent literature. At this point, reference is made only to DE-U-94 12 408 U1 as an
example.

There are some approaches which are quite promising, with respect to long-term stability in the patient's body, among the various hip stem endoprostheses proposed in the patent literature. Sooner or later, however, for example after 10 to 15 years, subjection of the endoprosthesis to wear and tear is to be observed, which leads to the necessity of a revision intervention to remove the implanted endoprosthesis and replace it by a new one. This is certainly not wholly without problems, since a considerable portion of the natural bone material is removed in the initial implantation by the resection and clearing of the bone marrow area. The material once removed is then under the circumstances absent in a revision intervention. This then especially has the effect that, when the patients are relatively young, which one must assume from the beginning, they will be subjected to at least one revision intervention in the course of their lives.

An endoprosthesis which manages with a smaller resection of natural bone material than the known hip stem endoprostheses has become known from DE-A-27 24 234 C2. The prosthetic element described therein is implanted in the upper region of a femur, but below the lesser trochanter, without a stem extending into the bone marrow area. This prosthesis, which is also designated as a pressure plate prosthesis, basically reaches with a proximal pressure plate over the cortex of the resected femur in the area of the removed hip joint head. It is braced with a pressure plate, which lies laterally on the femur, in such a manner that all mechanical forces between the endoprosthesis and the femur are directly introduced into the cortical layer of the femur, whereby a mechanical strain on the spongiosa, which is felt to be impermissible, should be avoided. Only a small amount of bone cement is necessary for fixing the pressure plate in the proximal region.

As explained, underlying the philosophy of this prosthesis is the assumption that the spongiosa of the femur should be subjected to as little strain as possible. This is achieved at the expense of an extreme load upon the cortex of the femur, since namely all forces are loaded onto it and introduced into it. This in no way corresponds to natural conditions according to current knowledge.

Moreover, WO 89/11837 shows a prosthesis which operates quite similarly, in which the function of the proximal pressure according to the previously mentioned publication is undertaken by the specially constructed hip joint head, which is provided with an interior recess on which the resected femur stump is installed in the interior with creation of pressure.

Two prostheses, in which the main burden of the spongiosa of the femur bone is to be assumed, have become known from FR 26 26 169 A1 and FR 26 74 122 A1. In the first of the two named publications, there is provided a proximal threaded bolt, having a plug-in cone, for screwing into the spongiosa. This may lead to severe instability problems within a very short time. In the second of the two named publications a plate bearing a plug cone is fastened by means of a series of bone screws, wherein the bone screws reach into the spongiosa. Serious stability questions also arise from this, since the spongiosa by its nature can only be subjected to slight point load in comparison with the cortex of the femur bone.

SUMMARY OF THE INVENTION

Against this background, it is therefore an object of the present invention to provide a femur endoprosthesis for an artificial hip joint, which is considerably better adapted than the aforementioned prostheses to natural conditions with respect to the introduction of force into the femur, wherein resections of natural bone material become necessary only to a small extent.

This object is accomplished according to the present invention in that the femur endoprosthesis has (1) a shell which can be implanted without cement in the upper region of a femur below the greater trochanter, the proximal end of the shell being connectable with an adapter for accommodating an artificial spherical joint, wherein the exterior of the shell is at least partially covered with an open-meshed three-dimensional spatial lattice structure, and (2) a shell end bent caudally and constructed as a stem end, which is at least partially covered with an open-meshed three-dimensional spatial lattice structure.

In contrast to German patent 196 01 340, in accordance with the present invention no draw plate is provided which works together with a draw-in bolt, which penetrates the cortex of the femur bone. This penetration leads to a weakening of the femur bone.

5 In the present case, the bent end of the shell is instead that part which lies laterally on the cortical side of the natural spongiosa. The implant of the invention is thus to be anchored "flying free" in the spongiosa of the femur, whereas the implant according to German patent 196 01 340 has a fixed point or fulcrum in the form of a draw plate.

10 In the present case, the result is that the femur bone is in no way weakened from the outside. The construction is moreover simpler than that in accordance with German patent 196 01 340. The attachment of an artificial spherical joint takes place in the same way with a corresponding adapter.

15 Further advantageous refinements are described below and in the dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

20 The foregoing summary, as well as the following detailed description of the invention, will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings embodiment(s) which are presently preferred. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities shown. In the drawings:

25 The single figure is a schematic view of a femur endoprosthesis according to the invention shown implanted in a femur bone and with attached spherical hip joint part.

DETAILED DESCRIPTION OF THE INVENTION

In the present invention, the shell 1' has a shape similar to the shell in accordance with German patent 196 01 340 with a conical taper from its proximal end 8' toward its distal end. In the distal area, however, the shell 1' is transitions into a stem end 30' bent caudally, that is bent downwardly, wherein the curvature is so proportioned that the outermost end of the stem end 30' comes to lie in a lateral area of the femur interior.

The shell 1' is at least partially covered with an open-meshed three-dimensional lattice structure 9' just like the stem end 30'. Open-meshed three dimensional lattice structure suitable for the endoprosthesis of the present invention are known in the art, for example from U.S. patents 5,178,201 and 5,433,750. Preferably, the lattice structure on shell exterior sides facing in caudal and cranial directions has a relatively coarse mesh, for example having mesh widths of about 2 to 6 mm, whereas the lattice structure on shell exterior sides facing in ventral and dorsal directions is preferably formed with a relatively fine mesh, for example having mesh widths of about 1 to 2.5 mm.

The attachment of an artificial spherical joint part 20' takes place with an adapter 2' constructed as a double plug cone, in the same manner as is provided in German patent 196 01 340. The double plug cone preferably has a peripheral flange 11' around a common base of the double cone, and the proximal end 8' of the shell 1' is provided with a conical sleeve 10' corresponding in shape to one end of the double plug cone for receiving and holding the adapter 2' with a pressure fit. Outward facing surfaces of the flange 11' may also be at least partially covered with an open meshed three-dimensional spatial lattice structure 12'.

As is clearly recognizable, no part of the implant penetrates the cortex of the femur bone 40', so that no weakening of the bone material takes place in this area. In cases where the femur endoprosthesis of the invention can be implanted, a more stable femur results.

It will be appreciated by those skilled in the art that changes could be made to the embodiment(s) described above without departing from the broad inventive concept thereof. It is understood, therefore, that this invention is not limited to the particular embodiment(s) disclosed, but it is intended to cover modifications
5 within the spirit and scope of the present invention as defined by the appended claims.

CLAIMS

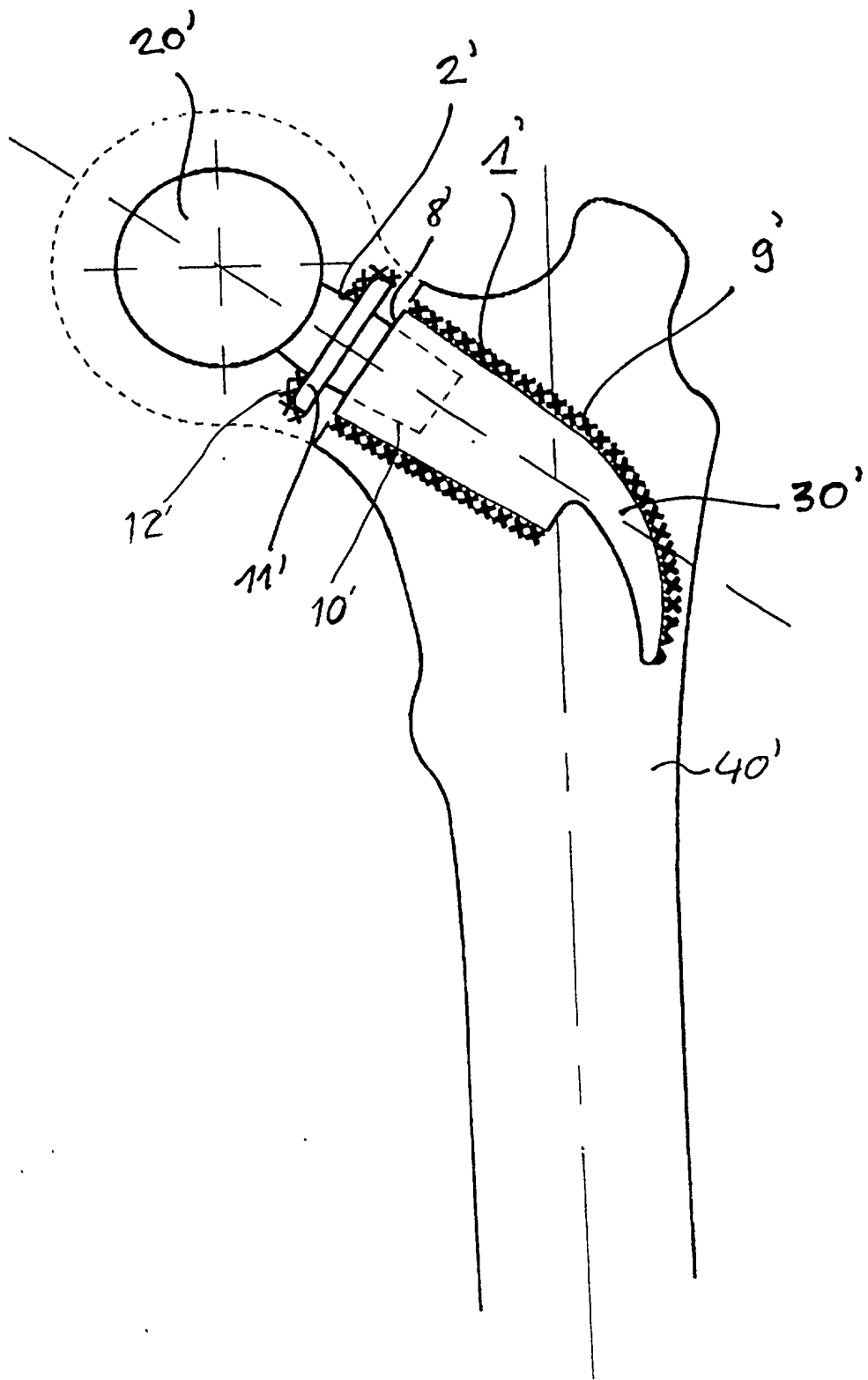
We claim:

1. A femur endoprosthesis for an artificial hip joint, comprising a shell (1') implantable without cement in an upper region of a femur (40') below the greater trochanter, a proximal end (8') of the shell being connectable with an adapter (2') for accommodating an artificial spherical joint part (20'), a distal end of the shell
5 being bent caudally and constructed as a stem end (30'), an exterior of the shell and the stem end thereof being at least partially covered with an open-meshed three-dimensional spatial lattice structure (9').
2. The femur endoprosthesis according to claim 1, wherein the shell (1') is formed with a conical taper from its proximal end (8') up to a beginning of
10 the bend of stem end (30').
3. The femur endoprosthesis according to claim 1, wherein the spatial lattice structure (9') is formed on shell exterior sides facing in caudal and cranial directions with a coarse mesh having mesh widths of about 2 to 6 mm.
4. The femur endoprosthesis according to claim 1, wherein the
15 spatial lattice structure (9') is formed on shell exterior sides facing in ventral and dorsal directions with a fine mesh having mesh widths of about 1 to 2.5 mm.
5. The femur endoprosthesis according to claim 1, wherein the adapter (2') for the spherical joint part (20') is constructed substantially as a double plug cone having a peripheral flange (11') around a common base of the double cone
20 wherein a conical sleeve (10') corresponding in shape to one end of the double plug cone is provided in a proximal area of the shell (1').

6. The femur endoprosthesis according to claim 5, wherein outward-facing surfaces of the flange (11') are at least partially covered with an open-meshed three-dimensional spatial lattice (12').

THE UNIVERSITY OF CHICAGO

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Attorney Docket No. 8056-80
(E 1875)

DECLARATION AND POWER OF ATTORNEY
(Original Application)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

FEMUR ENDOPROSTHESIS FOR ARTIFICIAL HIP JOINT

the specification of which is attached hereto and/or was filed on _____ as Application No. _____.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to herein.

I acknowledge the duty to disclose information which is material to patentability in accordance with Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d), of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

FOREIGN PRIORITY APPLICATION(S)

<u>197 20 493.7</u>	<u>Germany</u>	<u>16 May 1997</u>
(Number)	(Country)	(Day/month/year filed)
_____	_____	_____
(Number)	(Country)	(Day/month/year filed)

Priority Claimed
☒ Yes ☐ No

☐ Yes ☐ No

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional patent application(s) listed below and have also identified below any United States provisional patent application(s) having a filing date before that of the application on which priority is claimed:

PROVISIONAL PRIORITY PATENT APPLICATION(S)

		<u>Priority Claimed</u>
		<u>[] Yes [] No</u>
_____	_____	
(Application No.)	(Filing Date)	
_____	_____	
(Application No.)	(Filing Date)	<u>[] Yes [] No</u>

And I hereby appoint the registered attorneys and agents associated with **Panitch Schwarze Jacobs & Nadel, P.C., Customer No. 000570**, as my attorneys or agents with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Address all correspondence to **Customer No. 000570, namely, PANITCH SCHWARZE JACOBS & NADEL, P.C.**, One Commerce Square, 2005 Market Street, 22nd Floor, Philadelphia, Pennsylvania 19103-7086. Please direct all communications and telephone calls to **William W. Schwarze** at 215-965-1270.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

When Grounded

Investor's Signature _____

L. F. L.

Date

Litch, L. 6 V. 38

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Clampship

Post Office Address

Fluoride Stress 19

ZUSCHLUSSE

Full name of second job:

Investment, if any

Walter Dill

Inventor's Signature

Woburn & Maiden

Date _____

Роман, б.т. 98

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Power Index

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Comment

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1-00135 Return July

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Inventor's Signature _____

Date _____

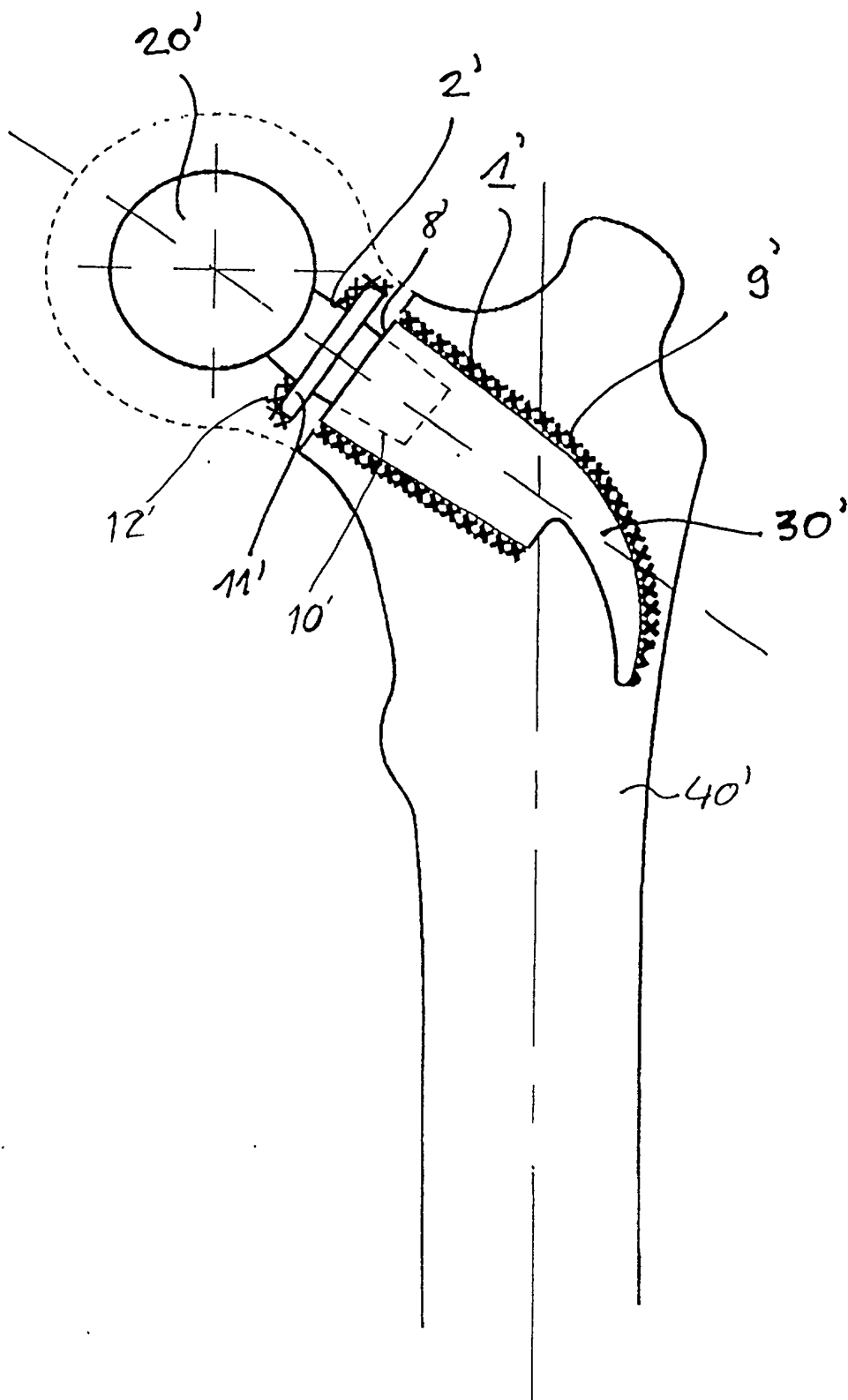
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669,440 349,200



If the rights held by the small business concern are not exclusive, each individual concern or organization having rights to the invention is listed below* and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 CFR 1.9(d) or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27)

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

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May 6, 1998
(DATE)

H. Grunzel
(SIGNATURE)